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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/705,840 11/06/00 DREWE

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HM12/0605
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EXAMINER

ROBINSON, R

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/705,840

Applicant(s)

DREWE ET AL.

Examiner

Binta M. Robinson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 15, 17, 19, 20, 22, 24, 29, 31, 56, 59, 61, 73, 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11-14, 16, 18, 21, 23, 25-28, 30, 32-54, 57, 58, 60, 63-72 and 75-78 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1-7,9,11-14,16,18,21,23,25-28,30,32-47,49-51,53,54,57,58,60,63-72 and 75-78.

DETAILED ACTION

The applicant's election of species, 2-amino-3-cyano-4-(3-bromo-4,5-dimethoxyphenyl)-4H-indolo[4,5-b]pyran at paper no. 6 without traverse is noted. The election of species will be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U. S. C. 121.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 9, 11-14, 16, 18, 21, 23, 25-28, 30, 32-47, 49-51, 53-54, 57-58, 60, 63-72, drawn to the formula I in claim 1 where Y is CN, A is phenyl or carbocyclic aryl, B is indolo, X is O, Z is NR₈R₉, and R₈ and R₉ are hydrogen, classified in class 548, subclass 430.
- II. Claims 1-78, drawn to the formula I in claim 1 where the radicals are all moieties not defined in group I, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the

Is this allowable if he fixes claim 7 & 8

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reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

As a result of applicant's election, Group I which encompasses the election of species will be examined.

Claims 8, 10, 15, 17, 19, 20, 22, 24, 29, 31, 48, 52, 55-56, 59, 61, 62, 73, and 74 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 11-14, 16, 18, 21, 23, 25-28; 30, 32-47, 49-51, 53-54, 57-58, 60, 63-72, 75-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the radicals Rx and Ry of formula I in claim 1 taken together with nitrogen to form all heterocycles, R8 and R9

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combined together with the group attached to them to form all heterocycles, A equal to all aryl, heteroaryl, saturated carbocyclic, partially saturated carbocyclic, saturated heterocyclic, partially saturated heterocyclic or arylalkyl groups, and B equal to all optionally substituted aromatic rings or all optionally substituted heteroaromatic rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various cancers mentioned. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. *keep*

The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 13, the phrase "Rx and Ry are taken together with the nitrogen to form a heterocycle" is indefinite because it is so broad. All other occurrences of the term "heterocycle" in claim 1 are also indefinite. Which heterocycle is the applicant claiming? ✓

B. In claim 1, lines 18-20, the phrase "A is optionally substituted and is aryl, heteroaryl, saturated carbocyclic, partially saturated carbocyclic, saturated heterocyclic, partially saturated heterocyclic or arylalkyl" is indefinite. Terms such as "heteroaryl" are so broad as to render the claim meaningless. What heteroaryl rings, for example, is the applicant claiming? ✓

C. In claim 1, lines 21-22, the phrase "B is an optionally substituted aromatic ring or an optionally substituted heteroaromatic ring" is indefinite. What aromatic ring or heteroaromatic ring is the applicant claiming? ✓

3. The IDS filed 4/16/01 has been considered.

4. The elected species appears to be allowable.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-223.

A handwritten signature in black ink, appearing to be 'BMK' with a stylized flourish at the end.

June 4, 2001